REMARKS

Claims 1-3, 7-12, 14-24 and 27-41 are currently pending in the present application. Claims 1 and 27 are the only independent claims.

Claims 1-3, 7-12 and 14-24 have been amended without prejudice. The amendments are formal in nature and are supported by the specification and claims as originally filed.

Claims 13 is cancelled and replaced with new claim 27 to better conform with the USPTO claim format. Claims 25 and 26 are cancelled to avoid redundancy with claims 27 and 14, respectively.

New claims 27-41 are added to better claim the invention at various scopes. The new claims are supported by the specification and claims as originally filed. For example, claim 27 is supported by original claims 13 and 25; claims 28 and 29 are supported by original claim 2; claims 30 and 31 are supported by original claim 3; claim 32 is supported by original claim 9; claim 33 is supported by original claim 10; claims 34 and 35 are supported by original claim 11; claims 36 and 37 are supported by original claim 16; claim 38 is supported by original claim 18; claims 39, 40 and 41 are supported by original claims 22, 23 and 24, respectively.

Because the amendments do not add any new matter to the application, entry of the amendments is respectfully requested.

Claim Rejections – 35 U.S.C. §112 and 35 U.S.C. §101

The Examiner has rejected claims 2, 3, 9, 11 and 13-26 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, 25 and 26 are cancelled. Claims 2, 3, 9, 11 and 14-24 have been amended to better conform with the USPTO claim format. Reconsideration and withdrawal of the rejection are respectfully requested in view of the present Amendment.

The Examiner has also rejected claims 13-24 under 35 U.S.C. § 101 because of the improper definition of a process.

Upon entry of the present Amendment, claim 13 is replaced with new claim 27. Claims 14-24 now depend, directly or indirectly, from claim 27, which is a process claim conforming with the USPTO format. Reconsideration and withdrawal of the rejection are respectfully requested in view of the present Amendment.

Claim Rejections – 35 U.S.C. §103

The Examiner has rejected claims 1-3, 7-9, 11-13 and 25 under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of U.S. Patent Application Publication No. 2003/0107149 ("Yang") in view of U.S. Patent No. 6,099,863 ("Gilis").

Applicants respectfully submit that a combination of Yang and Gilis does not render the presently claimed invention *prima facie* obvious, at least because the references, alone or in combination, do not teach or suggest a film-shaped medicament that is soluble in an aqueous medium and/or rapidly disintegrates in an aqueous medium, but is not mucoadhesive, for buccal administration of galanthamine or its salts or derivatives. The references do not render the presently claimed invention obvious further because the presently claimed invention achieves a rapid onset of action of galanthamine without the occurrence of unacceptable peripheral side effects, which is unexpected in view of the prior art direct-release formulations.

Yang describes thin films with non-self-aggregating uniform heterogeneity. It generally describes the use of the thin films for oral, anal, vaginal or ophthalmological administration (para. [0154]) of a wide variety of medications and pharmaceutical compositions, including cholinesterase inhibitors (para. [0099]). It teaches administration via mucous membranes (para. [0154]) using mucoadhesive compositions or films adhering to the oral cavity (paras. [0155] and [0156]), i.e., mucoadhesive formulations. Yang does not specifically teach or suggest to use the thin films for buccal administration of galanthamine or its salts or derivatives, let alone to use a thin film that is not mucoadhesive for the buccal administration, as recited in the present claims.

The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994). Yang's general disclosure on using its thin films for administration of cholinesterase inhibitors is not sufficient by itself to render the presently claimed invention *prima facie* obvious, at least because the result of buccal administration of galanthamine or its salts or derivatives by a filmed formulation is unpredictable. In view of the peripheral side effects associated with other direct-release dosage forms of galanthamine, one skilled in the art might have expected similar or even worse side effects from a filmed formulation that directly releases galanthamine in the region of the oral cavity. See para. [0013] to para. [0019]. Thus, one would not have been motivated to use Yang's thin films, let alone a filmed formulation that

is not mucoadhesive, for buccal administration of galanthamine or its salts or derivatives, as recited in the present claims.

Gilis does not compensate for the defects of Yang. Gilis describes tablets containing a therapeutically effective amount of galanthamine hyrdobromide. According to Gilis, in order to obtain government approval to market a drug, the formulation must produce reproducible results in various patients, e.g., it is prerequisite that the tablets disintegrate and dissolve within a particular period of time to a particular degree (col. 2, lines 56-60). The tablets in Gilis have a dissolution of at least 80% after 30 minutes (col. 2, lines 60-63). Gilis states that "compliance with this dissolution specification is **only** met by using a **particular diluent** containing a disintegrant, and a second disintegrant" (col. 2, lines 65-67). Gilis does not teach or suggest to use its tablets for buccal administration, i.e., releasing the active substance in the region of the oral cavity, so that the active substance can be absorbed via the oral mucosa (i.e., transmucosal absorption). One skilled in the art would not be motivated to replace Gilis' tablets with a film-shaped medicament that is not mucoadhesive for buccal administration of galanthamine, at least because any departure from the formulation or process taught by Gilis may change the dissolution of the formulation, thus affect the reproducibility required for government approval to market the drug.

In view of Yang and Gilis, one skilled in the art would not be motivated to use a filmed-medicament, let alone one that is not mucoadhesive, for buccal administration of galanthamine or its salts or derivatives with a reasonable expectation of success to achieve a rapid onset of action of galanthamine without the occurrence of unacceptable peripheral side effects associated with other fast release formulations. Only through innovative experimentation, Applicants discovered that such desirable result was surprisingly achieved by the presently claimed filmed-medicament.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-3, 7-9, 11-13 and 25 under 35 USC 103(a) as being unpatentable over Yang in view of Gilis.

The Examiner has rejected claims 1-3, 7-13, 25 and 26 under 35 U.S.C. § 103(a) as being unpatentable over the combined disclosures of Yang in view of Gilis and U.S. Patent No. 5,904,929 (" Uekama").

As discussed above, Yang and Gilis do not render the presently claimed invention *prima facie* obvious. Uekama does not compensate for the defects of Yang and Gilis. Uekama describes a pharmaceutical composition for trans-mucosal or transdermal administration wherein a per-C_2-18 acylated cyclodextrin is used as a drug reservoir or carrier. It discloses in general that the formulation can be used for administration of a range of active agents, including galanthamine. The dosage form according to Uekama is mucoadhesive (see for example col. 2, lines 31-39). In particular, Uekama teaches that the presence of paracylated cyclodextrin increases the adhesion of film-formed medicaments to mucosa. Uekama does not contain any specific teaching or suggestion on using a film-shaped medicament that is soluble in an aqueous medium and/or rapidly disintegrates in an aqueous medium, but is not mucoadhesive, for buccal administration of galanthamine or its salts or derivatives.

Similar to that discussed above for Yang and Gilis, Uekama's general disclosure on a pharmaceutical composition for trans-mucosal or transdermal administration of galanthamine, alone or in combination with the disclosures of Yang and Gilis, is not sufficient to render the presently claimed invention obvious, because of the lack of specific teachings in the prior art references, the unpredictability of the art of galanthamine formulation, and the unexpected superior result achieved by the presently claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-3, 7-13, 25 and 26 under 35 USC 103(a) as being unpatentable over Yang in view of Gilis and Uekama.

For the same reasons as that discussed above, new claims 27-41 are also not obvious over Yang, Gilis and Uekama, alone or in combination.

It is respectfully submitted that the present application, including claims 1-3, 7-12, 14-24 and 27-41, is in condition for allowance and such action is respectfully solicited. Applicants appreciate the effort of the Examiner and look forward to receiving the Notice of Allowance of all the pending claims.

Respectfully submitted,

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12/28/2009 By:
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